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A Comparison of Urinalysis Technologies for Drug Testing in Criminal Justice

by Christy Visher and Karen McFadden

Need for the study

It was once widely believed that drug users engaged primarily in minor property crimes to finance their habits. Recent research, however, indicates that the links between drugs and crime go well beyond minor theft. In fact, data from the National Institute of Justice's Drug Use Forecasting (DUF) Program in 1990 show that a majority of persons charged with serious property offenses and most types of violent crime test positive for illegal drugs at arrest. Moreover, several studies completed over the last decade indicate quite clearly that the most frequent, serious offenders are also the heaviest drug users. Surveys of State prison inmates conducted by the Bureau of Justice Statistics have found that over 40 percent of inmates report using illegal drugs on a daily or near-daily basis in the month before incarceration (see References).

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Faced with large numbers of offenders who use illegal drugs, criminal justice officials have been using drug testing as a tool for improving decisions and reducing criminal activity. Indeed, the President's 1991 National Drug Control Strategy emphasizes drug testing through urinalysis as a priority for identifying and monitoring the drug-involved offender and encourages all States to implement offender drug testing. Criminal justice is using drug testing at a number of stages: on arrest, during the pretrial release period, in jails and prisons, and during probation and parole.

Given the expanded use of drug testing in the criminal justice system, practitioners need comparative information about the use and accuracy of urinalysis technologies. Agencies implementing drug testing programs may have concerns about the relative accuracy of different tests and whether accuracy varies by type of drug. Practitioners may lack unbiased information about the different types and frequency of errors occurring in drug testing. In addition, drug testing technologies may vary in ease of use, suitability for use as a screening test, and relative costs.

This report summarizes the first study to compare four commonly used urine testing technologies using specimens gathered from a criminal justice population.[1] It assumes basic knowledge about urine testing methods and procedures. For information about uses of urine tests for criminal justice populations, guidelines for conducting urine tests in criminal justice settings, and legal issues, see the list of publications at the end of this report.

Purpose of the study

The primary goal of this study is to give decisionmakers in the criminal justice system clear and concise information that will help them make informed decisions about available urinalysis technologies. The need for such information led the Bureau of Justice Assistance and the National Institute of Justice, Office of Justice Programs, U.S. Department of Justice, to formulate and jointly fund a study of the technologies used in criminal justice settings to detect illegal drugs in urine.

Urine specimens were obtained from parolees as part of ongoing supervision

[1] The full report, *A Comparison of Urinalysis Technologies for Drug Testing in Criminal Justice*, discusses the study design; describes the two basic types of urinalysis technologies, immunoassay and chromatography; presents extensive data from the study; summarizes the study's conclusions and policy recommendations; and includes references and a technical glossary.

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requirements. Each sample was tested with four analytical procedures or technologies routinely used to detect drugs in urine. The study also collected urine specimens from a small group of arrestees. The results were then compared against gas chromatography/mass spectrometry (GC/MS), the most accurate method of drug detection. Analysis and comparison of test results provide answers to the following questions:

- How accurate are the technologies? Does one particular technology result in more false positive or false negative errors than others?
- Do the existing Federal guidelines for drug testing in the workplace, especially for cutoff levels, meet the needs of the criminal justice system?
- Is one technology consistently accurate enough to eliminate the need for routine confirmation by an alternative method?
- Do technologies exist that can be used by paraprofessionals in a criminal justice operational environment?

The answers to these questions will give criminal justice practitioners the detailed information they need to make informed decisions about the advantages and shortcomings of each of the technologies.

This executive summary presents the principal findings and briefly discusses some of the policy implications of the study. Interested readers can refer to the full report for a complete discussion of the study's methods and results and the implications of using urine testing technologies to detect drug use in criminal justice populations.

Study design

Five analytical procedures were used to analyze 2,668 urine specimens from parolees and arrestees; each sample was screened for opiates, cocaine, phencyclidine (PCP), amphetamines, and marijuana. The analytical procedures were EMIT™, TDx™ FPIA, Abuscreen™ RIA, standard thin-layer chromatography (TLC),[2] and gas chromatography/mass spectrometry. These procedures were chosen because they were in wide use at the time of the study. Three manufacturers of the immunoassays provided free reagents (test chemicals), test instruments, and training for the study. These manufacturers were Abbott Laboratories, manufacturers of TDx™ FPIA; Roche Diagnostic Systems, Inc., manufacturers of Abuscreen™ RIA; and Syva Company, manufacturers of EMIT™.

Laboratory technicians used GC/MS, the most sensitive and accurate of the urinalysis technologies, as the standard against which results from the four other technologies were compared. GC/MS is recognized by the drug testing industry as the preferred confirmatory technology for detecting drugs in urine.

The concentration of drugs in urine is measured in nanograms (billionths of a gram) per milliliter of liquid (ng/mL) of the drug or of the drug metabolite formed in the body as a result of the ingestion of a specific drug. The "cutoff level" is that concentration, stated in ng/mL, used to determine whether a specimen is positive or negative.

The primary study results were based on the screening and GC/MS cutoff levels specified by the National Institute on Drug Abuse (NIDA) of the U.S. Department of Health and Human Services. In two instances, different cutoff levels were used because the EMIT™ technology did not have tests available using the cutoffs in the guidelines at the time of the study (see table 1).[3]

These guidelines were formulated for Federal employee drug testing and specifically exclude drug testing in the criminal justice system; however, criminal justice agencies—along with the private sector, commercial laboratories, and manufacturers of drug testing products—have relied on the NIDA guidelines for direction in establishing and implementing drug testing programs.

If a urine specimen showed a drug present in a concentration at or above the GC/MS cutoff level established by NIDA, the sample was considered

[2] Standard thin-layer chromatography should not be confused with high-performance thin-layer chromatography (HPTLC) or toxiLab™, an onsite version of HPTLC, neither of which was examined in this study. The results obtained using standard TLC in this study cannot be generalized to the other technologies.

[3] Since the study began, Abbott Laboratories has modified some of its assays for marijuana, PCP, and amphetamines; and the products used in this study are, in some cases, no longer available. In addition, Syva Company has recently introduced a specialized assay for detecting amphetamines. It is not known how these new or modified products would compare to those used in the study.

Table 1
NIDA and Study Cutoffs for Immunoassays (Screening Tests) and GC/MS

Drug	Immunoassays	GC/MS
Marijuana	100	15
Cocaine	300	150
Phencyclidine	25[a]	25
Opiates	300	300
Amphetamines	1,000[b]	500

[a] for EMIT, 75 ng/mL
[b] for EMIT, 300 ng/mL

positive for that drug. If the GC/MS results showed a drug concentration below the cutoff, the specimen was considered negative for that drug. The test results of the four technologies were compared individually to the GC/MS results to determine their accuracy.

The study also examined the extent to which drug use may be missed in criminal justice populations. Additional analyses used cutoff levels lower than the concentrations in the NIDA guidelines to determine whether a specimen was positive or negative. Lower cutoff levels lead to more positive test results since a urine specimen containing a smaller amount of the drug would be considered positive.

All urine specimens were sent to the onsite drug testing facility operated in the Alhambra Parole Office, part of the California Department of Corrections, where technicians performed the EMIT™ and the TDx™ tests. A portion of each urine specimen was reserved and sent to BPL Toxicology Laboratory in Tarzana, California, for analysis using RIA, TLC, and GC/MS technologies. No results were shared between the onsite testing facility and the BPL Laboratory.

Study results

Accuracy of the technologies

Test results show a clear difference between the accuracy of the immunoassays as a group—EMIT™, TDx™, and RIA—and thin-layer chromatography. *Standard thin-layer chromatography performed poorly in identifying the presence of illegal drugs.*

TLC identified only 8 to 19 percent of the specimens containing opiates, cocaine, amphetamines, and PCP (in amounts at or above the NIDA cutoffs according to GC/MS) and only 48 percent of the specimens containing marijuana. All three immunoassays were more accurate than TLC. Among the immunoassays *no one type of immunoassay is consistently superior in identifying positive and negative urine specimens for the five drugs.*

A concern frequently voiced about drug testing is the possibility that the urinalysis technology being used will label as positive a urine specimen from an individual who has not used drugs. These errors are known as false positives. The study's average false positive rate, combining results for the five drug types and using the NIDA cutoff levels, was about 1 to 2 percent, based on the initial screening test, without GC/MS confirmation (see figure 1).

GC/MS confirmation of positive results from screening tests would eliminate virtually all false positive errors. However, GC/MS testing is too expensive for routine confirmation of all positive screening results in a criminal justice setting.[4]

The study also examined the extent to which the current screening technologies miss the presence of drugs in urine—that is, the extent of false negative errors. For the three immunoassays, the average false negative rate for the five drug types

[4]The study findings on false positive and false negative rates should not be the only criteria for selecting an immunoassay for use in a drug testing program. Many factors contribute to these findings and, in some cases, simply comparing the percentage of erroneous test results may be misleading. The full report discusses the study results in detail.

Confirmation test: A second test which is used to confirm positive results from an initial screening test. A confirmation test uses a different method than the screening test and provides a greater margin of certainty.

Cutoff level: The concentration of a drug in urine, usually in nanograms per milliliter (ng/mL), used to determine whether a specimen is positive (at or above the cutoff level) or negative (below the cutoff level) for the drug in question.

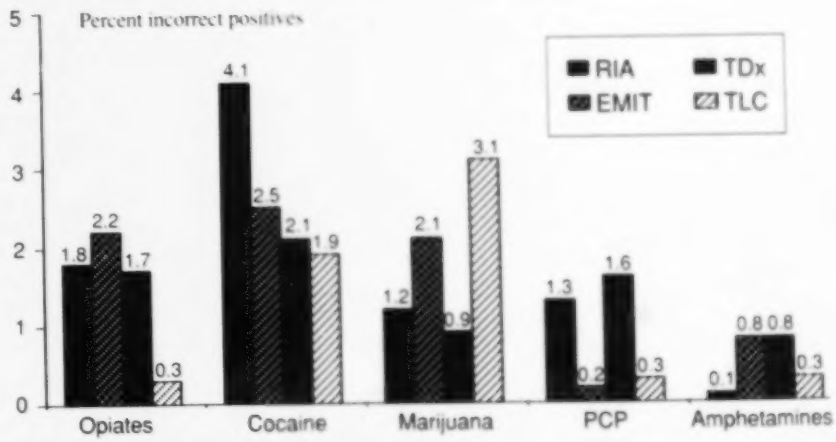
False positive: A test result indicating positive for a given drug when that drug is actually absent in a urine sample *or* present in concentrations below the designated cutoff level.

False negative: A negative test result for a given drug when that drug is present in a sample above the cutoff level for the test.

Screening test: An initial test which is used to detect drugs of abuse in urine. Screening tests are rapid and less expensive, but generally not as accurate as confirmation tests.

Figure 1

False Positive Rates* by Drug Type



*Negative by GC/MS but positive by screening test

was about 20 percent (using the NIDA screening cutoff levels in table 1). Screening tests are designed to minimize false positive results and, as a consequence, a larger number of false negative results will occur. Repeated testing of an individual on a weekly or monthly basis, however, most likely will detect illegal substances in a regular drug user.

The false negative rates for the five drugs are presented in figure 2. As the figure clearly shows, standard TLC incorrectly identified as negative a much higher proportion of urine specimens than did the three immunoassays.

The magnitude of the false negative rate was determined by the screening and confirmation cutoff levels, which followed the NIDA guidelines. A close examination of the data revealed that the immunoassay cutoffs were partly the reason for the technology's failure to identify the specimens designated as positive by GC/MS. Many of the false negative specimens contained some amount of the drug, but not at concentrations high enough for the immunoassays to label the specimen positive. Accordingly, the false negative rate would be reduced by lowering the immunoassay cutoffs.

Adequacy of current cutoff levels

A secondary objective of the study was to determine whether the current NIDA cutoff levels are appropriate for testing offenders since lower cutoff levels could lead to the detection of a greater number of drug users. To accomplish this analysis, screening and confirmation cutoffs were selected for marijuana, cocaine, and opiates that were lower than those specified by NIDA (see full report for details).

The NIDA cutoff level for screening urine specimens for marijuana is 100 ng/mL. Analysis indicated that if the cutoff levels for marijuana were lowered to 50 ng/mL, approximately *one-third more* users might be identified. Of 100 marijuana users in a group of probationers, the current standards would detect about 65 users; with the lower cutoff level, an additional 20 users might be detected.[5]

For cocaine and opiates, lowering the current NIDA screening cutoff levels to 200 ng/mL might increase detection of drug use by 10 to 20 percent.

These analyses show that some false negative test results would be considered positive if screening cutoff levels were lowered. The potential impact on drug testing programs could be considerable in the case of marijuana if more users tested positive. For cocaine or opiates, a smaller number of additional users would be identified if the cutoff levels for these drugs were lowered.

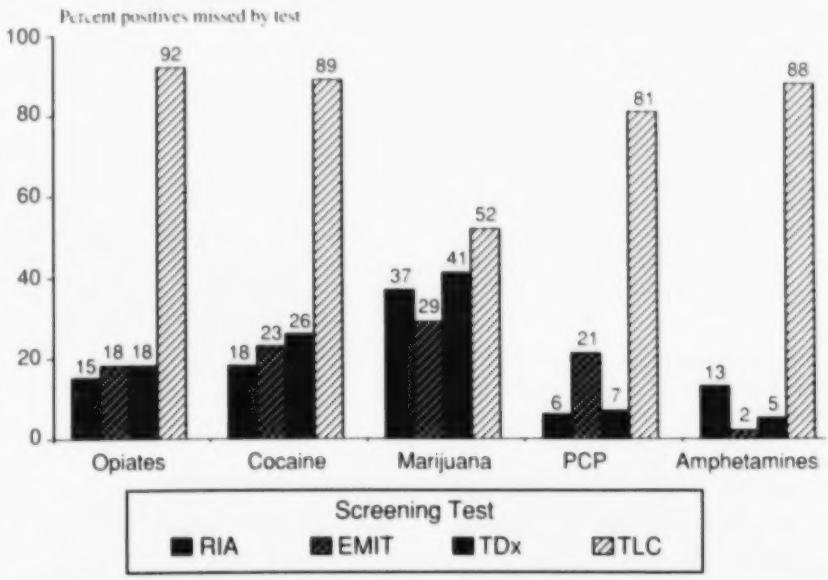
Users of urine tests must be knowledgeable about screening cutoff levels. Some criminal justice agencies may wish to use cutoff levels lower than those in the NIDA guidelines. Some manufacturers of urinalysis-based drug testing technologies allow the operator to select a cutoff level within a specified range. Others establish the cutoff level—usually that specified in the NIDA guidelines—at which a specimen is considered positive or negative.

Lowering cutoff levels would likely result in increases in the number of identified drug users. Therefore, before opting to select lower levels, criminal justice agencies must consider several issues. The possible consequences might include an increased demand for drug treatment, an increased need for additional supervision of drug-using offenders, and a greater need for jail and prison space for probation and parole revocations.

It might be argued that the cutoff levels in the NIDA guidelines are appropriate because these cutoff levels are already identifying the vast majority of drug-involved offenders in pretrial, probation, and parole testing. Moreover, in some jurisdictions, "scientifically acceptable" cutoff levels may have already been established by State law or regulation.

Figure 2

False Negative Rates* by Drug Type



*Positive by GC/MS but negative by screening test

[5] This example assumes that the concentration of marijuana metabolites in the tested population is similar to those found among individuals in this study.

At a minimum, drug testing programs in criminal justice agencies should ensure that cutoffs are set at levels that the manufacturer of the test believes to be legally defensible. The manufacturer's outlined procedures, such as preparation of reagents, should also be strictly followed to obtain maximum accuracy. Little research is available to guide the criminal justice community on how much of a given drug should be present in the urine sample before the specimen can be declared positive. Established cutoffs, such as those in the NIDA guidelines, ensure continuity of drug testing procedures among jurisdictions and uniform testing of all offenders.

The issue of confirmation

Immunoassay urinalysis technologies for drug testing are not error-free. False positive test results will occur with any immunoassay technology. In practice, of 100 negative urine specimens tested using 1 of the immunoassays examined in this study, an average of 1 or 2 specimens may test positive.

Confirmation of initial immunoassay positives by an alternate method—preferably GC or GC/MS—is recommended by the NIDA guidelines to avoid testing errors. In many criminal justice settings, officials consider as confirmation an individual's admission of drug use after being confronted with a positive drug test. If an individual contests a positive result from a screening test, however, and if that positive drug test will lead to serious punitive action, confirmation by GC/MS provides the best protection against future legal challenges. Users of urine tests must weigh the consequences of testing errors against the time and expense involved in confirming positive test results with GC/MS.

Repeat testing of urine specimens by the same method—or confirmation of screened positives using a similar technology—probably will not eliminate all erroneous results. For instance, using another type of immunoassay if the initial screen was also an immunoassay may eliminate faulty procedural results, but not the errors inherent in the technology. This repeat practice is not considered a scientific confirmatory result, but courts in some jurisdictions have allowed this type of confirmation. Any criminal justice agency considering the implementation of a drug testing program should review the relevant case law about confirmation of drug test results.

Onsite versus laboratory testing

The study results show that the two immunoassay technologies carried out by trained staff in an onsite testing facility (EMIT™ and TDx™ FPIA) are just as accurate as the immunoassay procedure performed by certified technicians in a commercial laboratory (Abuscreen™ RIA).

Although the quality of services provided by onsite testing facilities can vary greatly, many such facilities are comparable to full-service laboratories. Drug testing performed in an onsite facility using technologies designed for onsite use can be just as accurate as testing performed in a full-service laboratory. It is critical to maintain appropriate testing procedures and protocols, including chain of custody and quality control, and personnel training.

Final note

This study was designed to provide guidance on urinalysis technologies for drug testing in the criminal justice system—for arrestees, those on pretrial release, probationers, incarcerated offenders, and parolees. Some of the findings may be dependent upon the higher levels of illegal drug use in these populations than in the general population. Results should *not* be generalized to military personnel, Federal employees, pilots, railroad employees, job applicants, or other such populations. Drug testing policies for many of these groups are governed by guidelines specific to their needs.

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Several agencies and organizations participated in the study: the Public Health Foundation of Los Angeles County, Inc., which served as a pass-through agency for the project funding; the State of California Department of Corrections, Alhambra Parole Office, conducted onsite urinalysis of the specimens; the San Diego Association of Governments provided additional urine specimens from a group of arrestees for the study; and BPL Toxicology Laboratory analyzed specimens using RIA, TLC, and GC/MS technologies. We would also like to thank Abbott Laboratories, Roche Diagnostic Systems, Inc., and Syva Company for providing free reagents, instrumentation, and training for the study.

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References and related documents

Bureau of Justice Assistance (1991). American Probation and Parole Association's *Drug Testing Guidelines and Practices for Adult Probation and Parole Agencies*. Washington, DC: Bureau of Justice Assistance.

Bureau of Justice Assistance (1989). *Estimating the Costs of Drug Testing for a Pretrial Services Program*. Washington, DC: Bureau of Justice Assistance.

Bureau of Justice Assistance (1991). *Integrating Drug Testing Into a Pretrial Services System: Program Brief, Implementation Guide*. Washington, DC: Bureau of Justice Assistance (forthcoming).

Bureau of Justice Statistics (1988). *Drug Use and Crime*. Washington, DC: Bureau of Justice Statistics.

Wish, Eric, and Gropper, Bernard (1990). "Drug Testing by the Criminal Justice System: Method, Research, and Application," *Crime and Justice, Vol. 13: Drugs and Crime*. Chicago, IL: University of Chicago Press.

Wish, Eric, Dupont, Robert, and Gropper, Bernard (1991). *Urine Testing of Offenders: A Manual for Practitioners*. Washington, DC: National Institute of Justice (forthcoming).

Available from the National Criminal Justice Reference Service, Box 6000, Rockville, MD 20850, 800–851–3420.

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